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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 22, 2010
Submitter:	GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. 9900 Innovation Drive Wauwatosa, WI, USA 53226
Primary Contact Person:	Bryan Behn, Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. Phone: 414-721-4214 Fax: 414-918-8275
Secondary Contact Person:	Jim Turner Regulatory Affairs Manager GE Healthcare Phone: 262-544-3359 Fax: 414-908-9225
Device: Trade Name:	4D-VIEW 9.1
Common/Usual Name:	4D-VIEW
Classification Names:	Class II CFR 892.2050, LLZ
Product Code:	Picture Archiving and Communication Systems, 21 CFR 892.2050
Predicate Device(s):	K050943 Viewpoint 5.0 K061682 Voluson E8
Device Description:	4D View 9.1 is a standalone Software product, which can be installed only on a PC with Microsoft Windows Vista operating systems: Primary Operating Functions are: • Display and editing of GE Ultrasound 3D/4D data sets • Measurements on displayed image incl. derived calculations which are all based on medical literature in the following applications: Abdominal, Obstetrics, Gynecology, Cardiology, Urology, Vascular, Neurology, Small Parts, Pediatrics, Musculo-Skeletal (Orthopedics). • Data storage (image, measurement and patient data) • Data transfer to and from remote systems (e.g. via DICOM) • Adding annotations to acquired image Same measurements and calculations are available on the predicate devices
Intended Use:	Image Display of GE Ultrasound 3D/4D ultrasound data sets for diagnostic purposes including measurements on displayed image.

Technology: The 4D VIEW 9.1 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The 4D VIEW 9.1 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 4D-View 9.1, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the 4D-VIEW 9.1 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
9900 Innovation Drive
WAUWATOSA WI 53226-4856

OCT 07 2010

Re: K101166
Trade/Device Name: 4D-VIEW 9.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 22, 2010
Received: April 26, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K101166

Device Name: 4D-VIEW 9.1

Indications for Use:

Image Display of GE Ultrasound 3D/4D data sets for diagnostic purposes including measurements on displayed image.

Prescription Use__X__ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

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